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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,985	02/09/2004	Robert A. Rabiner	20563/2422	9583
26161	7590	11/23/2007		
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER SHAHRESTANI, NASIR	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 11/23/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/774,985	<b>Applicant(s)</b> RABINER ET AL.	
	<b>Examiner</b> Nasir Shahrestani	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-12,14,15,17-27,29,30,32,64-70 and 72-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12,14,15,17-27,29,30,32,64-70 and 72-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This action is responsive to Applicant's communication filed 6/21/2007.

Claims 76-78 have been added as new.

Claims 4,13,16,28,31,33-63,71 have been cancelled.

Claims 1-3, 5-12, 14-15, 17-27, 29-30, 32, 64-70, 72-78 are pending.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-3, 5-12, 14-15, 17-27, 29-30, 32, 64-70, 72-78, have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-3, 6-7, 9-11, 17, 19-22, 25-26, 32, 64-66, 68-69, 72-73, 76-78, are rejected** under 35 U.S.C. 103(a) as being unpatentable over Wuchinich (US 2001/0047166) in view of Sakurai et al (US 2003/0045887), in of Weng et al. (U.S. 5,269,297), and in further view of Kuris (U.S. 3,565,062). Wuchinich discloses an ultrasonic medical device that creates torsional vibration (figure 4, element 40), which discloses all of the limitations of the above mentioned claims. The probe comprises a proximal end coupled to a transducer (figure 1, element 1), a

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distal end, with a longitudinal axis between (figure 4), with an energy source engaged to the transducer producing ultrasonic energy (figure 1, elements 1 and 15). Torsional vibration, which by definition rotates and counter-rotates the ultrasonic probe, propagates the length of the probe through the resonator resulting in a plurality of nodes (paragraph 12), which inherently result in a plurality of anti-nodes at half the distance between any two nodes. In the embodiment shown in figure 3, the longitudinal axis of the probe has a radially asymmetric cross section (figure 3, element 41). It is also possible for the axis to have an approximately rectangular cross section (paragraph 70) or have longitudinal grooves, which create a plurality of “flutes”, or projections, extending along the length of the probe (paragraph 10). Additionally, the diameter of the probe can be tapered or varied from the proximal end to the distal end of the probe (figure 4).

Wuchinich, as discussed above, substantially discloses the invention as claimed, however fails to explicitly disclose operating at the resonant frequency of the transducer. Sakurai also discloses an ultrasonic probe capable of torsional vibration and teaches that “resonance-point tracking” is possible in order to set the resonance frequency to the frequency of the vibration oscillator (paragraph 77). Additionally, the elongated probe of the ultrasound device has an approximately circular cross section (figure 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich with the teachings of Sakurai to increase the efficiency of the device. However, Wuchinich in view of Sakurai et al. does not teach wherein the probe produces cavitation. In the same field of endeavor, Weng et al. teaches an ultrasonic transmission apparatus wherein the distal segment (element 16b) undergoes displacement at ultrasonic frequencies and driving the tip (element 18) at ultrasonic frequencies and producing cavitation (col. 14 lines 40-46). It would have been obvious to one of ordinary

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skill in the art at the time of the invention to have modify the device as disclosed by Wuchinich in view of Sakurai et al. and to have further included means for the ultrasonic probe to produce cavitation along the longitudinal axis in a medium surrounding the probe during use in order to destroy a thrombus in the patient's blood vessel. Furthermore, it would have been an obvious modification to one ordinary skill in the art to further include means for optimized energy propagation for the ultrasound transducer.

Wuchinich in view of Sakurai and Weng et al. do not specifically teach the use of a radially asymmetric cross section.

Kuris teaches an ultrasonic apparatus having an asymmetric tip (fig. 10) where the cross section of the tip gradually decreases in size, and has a stepwise decrease from the tubular catheter to the probe, being an obvious modification to one of ordinary skill in the art at the time of the invention.

**Claims 5 and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai, in further view of Weng as applied to claims 4 and 19, respectively, above, and further in view of Rabiner, et al (US 2002/0029054). Wuchinich in view of Sakurai, in view of Weng et al., as discussed above, substantially discloses the invention as claimed, however does not explicitly teach that the ultrasonic probe can be used to ablate biological material along the portion of the longitudinal axis comprising the radially asymmetric cross section. Rabiner teaches that it is advantageous to use ultrasonic vibration along the longitudinal axis of an ultrasonic probe to destroy tissue along the length of the probe (paragraph 26) using cavitation in order to be less traumatic to surrounding tissue. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device

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disclosed by Wuchinich in view of Sakurai, in further view of Weng et al. in light of the teachings of the reference by Rabiner to provide decreased procedure time and less residual tissue damage (paragraph 26).

**Claims 8, 12, 14-15, 24, 27, 29-30, 67, 70,** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai, in view of Weng et al. and further in view of Kuris as applied to claims 1, 19, and 64 above, and further in view of Fenton (US 2003/0212331). Wuchinich in view of Sakurai and in further view of Weng et al., as discussed above, substantially discloses the invention as claimed, however fails to disclose the capability for flexibility of the probe and fails to explicitly disclose the operating frequency range of the device. Fenton also discloses an ultrasonic device capable of torsional vibration, which states that ultrasonic surgical instruments typically operate in the range of 20 to 100 kHz (paragraph 4). In addition, the vibration element of the probe disclosed in the reference by Fenton is “formed of a flexible, compliant material” which may “have a substantially curvilinear configuration” (paragraph 19). In another embodiment the probe has a substantially uniform cross section (figure 2A). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in view of Sakurai, in further view of Weng et al. in light of the teachings of Fenton as flexibility and a curved shape in the probe allow the probe to reach a greater number of areas minimally invasively.

**Claim 18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai, in further view of Weng et al., in further view of Kuris as applied to claim 1 above, and further in view of Jones (US 6433464). Wuchinich in view of Sakurai, in further view of Weng et al. as discussed above, substantially discloses the invention as claimed,

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however fails to teach that the device may be disposable. Jones discloses a device for dissolving and removing unwanted biologic materials using acoustic waves and teaches one advantage of the device is that it is optionally disposable (col. 18, lines 59-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in view of Sakurai, in further view of Weng et al. with the teachings of Jones in order to make the probe disposable in order to provide a device that is more convenient to use and does not require cleaning or sterilization.

**Claims 74-75** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai, in further view of Weng et al., in further view of Kuris as applied to claims 1 and 19 above, and further in view of Hood (U.S. 5,935,142). Wuchinich in view of Sakurai, in further view of Weng et al. as discussed above, substantially discloses the invention as claimed, however fails to teach wherein a length of the probe is substantially equal to an integer multiple of a one-half wavelength of a torsional resonance of the transducer. However in the same field of endeavor, Hood teaches a cavitation-assisted method of material separation wherein the enlarged section (element 134) has a length equal to approximately a half wavelength with an anti-node positioned generally at the longitudinal center of the enlarged section. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in view of Sakurai, in further view of Weng et al. with the teachings of Hood in order to provide for optimal cavitation that would in turn provide for breakage of various thrombi.

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***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nasir Shahrestani whose telephone number is 571-270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*NB*  
NSS  
11/13/2007

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